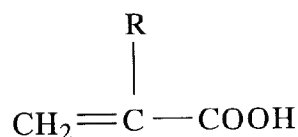


WHAT IS CLAIMED IS:

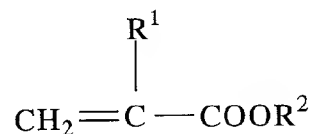
1. A topically applicable cosmetic/pharmaceutical oil-in-water emulsion including a discontinuous fatty phase dispersed in a continuous aqueous phase and comprising an effective amount of at least one biologically active agent (A) and an effective amount of an emulsifying system (B) therefor, said at least one biologically active agent (A) being non-solubilized therein in micronized particulate state, at least 80%, numerically, of said micronized particles having diameters ranging from 1 to 10  $\mu\text{m}$  and at least 50%, also numerically, having diameters of less than 5  $\mu\text{m}$ .
2. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, at least 90%, numerically, of said micronized particles having diameters ranging from 1 to 10  $\mu\text{m}$ .
3. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said emulsifying system (B) comprising at least one copolymerizate of a major amount of a monoolefinically unsaturated  $\text{C}_3\text{-C}_6$  carboxylic acid monomer, or anhydride thereof, with a minor amount of an acrylic acid fatty ester comonomer.
4. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 3, said emulsifying system (B) comprising at least one copolymerizate of 80% to 98% by weight of said monoolefinically unsaturated  $\text{C}_3\text{-C}_6$  carboxylic acid monomer, or anhydride thereof, with 20% to 2% by weight of an acrylic acid fatty ester comonomer.
5. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 3, said carboxylic acid monomer having the formula:



in which R is hydrogen, halogen, hydroxyl, a lactone group, a lactam group, a cyanogen (-C=N) group, a monovalent alkyl radical, an aryl radical, an alkylaryl radical, an aralkyl radical or a cycloaliphatic radical.

5

6. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 5, said ester comonomer having the formula:



10 in which R<sup>1</sup> is hydrogen, methyl or ethyl and R<sup>2</sup> is a C<sub>8</sub>-C<sub>30</sub> alkyl radical.

7. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 6, said carboxylic acid monomer comprising acrylic acid, methacrylic acid, or mixtures thereof, and wherein said ester comonomer, R<sup>1</sup> is hydrogen or  
15 methyl and R<sup>2</sup> is a C<sub>10</sub>-C<sub>22</sub> alkyl radical.

8. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 3, said at least one copolymerizate comprising an acrylic/C<sub>10</sub>-C<sub>30</sub>-alkylacrylate copolymer.

20

9. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 8, comprising from 0.05% to 2% by weight of said acrylic/C<sub>10</sub>-C<sub>30</sub> alkylacrylate copolymer.

10. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 3, comprising from 0.01 % to 3 % by weight of said at least one copolymerizate.

5 11. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, further comprising at least one surfactant emulsifier.

10 12. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 11, said at least one surfactant emulsifier comprising glyceryl or PEG-100 stearate, a polyoxyethylenated fatty acid ester, a polyoxyethylenated stearyl alcohol (2) combined with a polyethylenated stearyl alcohol (21), or mixture thereof.

15 13. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 11, further comprising at least one co-surfactant.

20 14. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 13, said at least one co-surfactant comprising a sorbitan ester, sorbitan sesquioleate, sorbitan isostearate, a fatty alkyl ether having a high HLB value, a fatty alkyl ether having a low HLB value, or mixture thereof.

15. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, comprising up to 15 % by weight of said emulsifying system (B).

25 16. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 15, comprising from 0.05 % to 8 % by weight of said emulsifying system (B).

17. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 16, comprising from 0.1% to 2% by weight of said emulsifying system (B).

5 18. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said at least one biologically active agent (A) being insoluble or difficultly soluble in water or a hydrophilic medium under pH conditions which are compatible with the skin.

10 19. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said at least one biologically active agent (A) comprising an agent which modulates skin differentiation and/or proliferation and/or pigmentation, an antibacterial agent, an antiparasitic agent, an antifungal agent, an antibiotic, a steroidal anti-inflammatory agent, a non-steroidal anti-inflammatory agent, an  
15 anaesthetic, an anti-pruriginous agent, an antiviral agent, a keratolytic agent, a free-radical scavenger, an antiseborrhoeic agent, an antidandruff agent, an anti-acne agent, an antimetabolite, an agent for combating hair loss and for promoting hair growth or vice versa, an antiseptic, or mixture thereof.

20 20. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 19, comprising from 0.0001% to 20% by weight of said at least one biologically active agent (A).

25 21. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 20, comprising from 0.025% to 15% by weight of said at least one biologically active agent (A).

22. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, comprising from 5% to 50% by weight of said discontinuous fatty phase.

5 23. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 22, comprising from 12% to 25% by weight of said at least one discontinuous fatty phase.

10 24. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said discontinuous fatty phase comprising a silicone fatty substance.

25. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 24, said silicone fatty substance comprising a poly(C<sub>1</sub>-C<sub>20</sub>)alkylsiloxane or one containing trimethylsilyl endgroups, a linear polydimethylsiloxane, an  
15 alkylmethylpolysiloxane, cetyldimethicone, a volatile silicone oil, a cyclic volatile silicone having from 3 to 8 silicon atoms, a cyclomethicone, cyclotetradimethylsiloxane, cyclopentadimethylsiloxane, cyclohexadimethylsiloxane, a cyclocopolymer, a dimethylsiloxane/methylalkylsiloxane, a linear volatile silicone having from 2 to 9  
20 silicon atoms, hexamethyldisiloxane, hexyl heptamethyltrisiloxane, octyl heptamethyltrisiloxane, a phenylsilicone oil, or mixture thereof.

26. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said discontinuous fatty phase comprising a non-silicone fatty oil,  
25 isohexadecane, a liquid paraffin, a liquid petroleum jelly, almond oil, perhydrosqualene, apricot oil, wheat germ oil, sweet almond oil, beauty-leaf oil, palm oil, castor oil, avocado oil, jojoba oil, olive oil, cereal germ oil, an ester of fatty acid or of a fatty alcohol, diisopropyl adipate, octyldodecyl myristate, a (C<sub>12</sub>-C<sub>15</sub>)alkyl benzoate, an acetyl glyceride, an alkyl or polyalkyl octanoate, a

decanoate or ricinoleate, a fatty acid triglyceride, a glyceride, a hydrogenated polyisobutene, a hydrogenated oil that is solid at 25°C, a lanolin, a fatty ester that is solid at 25°C, or mixture thereof.

5     27.     The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said discontinuous fatty phase comprising a fatty acid or fatty alcohol, or derivative thereof, a wax, or mixture thereof.

10     28.     The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, comprising from 30% to 95% by weight of said continuous aqueous phase.

15     29.     The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 28, comprising from 60% to 80% by weight of said continuous aqueous phase.

20     30.     The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said continuous aqueous phase comprising a floral water, cornflower water, a thermal spring water, a natural mineral water, eau de Vittel, a water from the Vichy basin, eau de Uriage, eau de la Roche Posay, eau de la Bourboule, eau d'Enghien-les-Bains, eau de Saint Gervais-les-Bains, eau de Nérès-les-Bains, eau d'Allevard-les-Bains, eau de Digne, eau de Maizières, eau de Neyrac-les-Bains, eau de Lons-le-Saunier, Eaux Bonnes, eau de Rochefort, eau de Saint Christau, eau des Fumades, eau de Tercis-les-Bains, eau d'Avène, eau d'Aix-les-  
25     Bains, or mixture thereof.

31.     The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, further comprising at least one wetting agent.

32. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 31, said at least one wetting agent comprising a poloxamer, an oxyethylenated sorbitol ester, a polysorbate, or mixture thereof.

5 33. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 31, comprising from 01.% to 10% by weight of said at least one wetting agent.

10 34. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 31, further comprising at least one pro-penetrating and/or wetting agent.

15 35. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 34, said at least one pro-penetrating and/or wetting agent comprising propylene glycol, glycerol, sorbitol, or mixture thereof.

36. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 34, comprising from 1% to 20% by weight of said at least one pro-penetrating and/or wetting agent.

20 37. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, further comprising at least one gelling agent.

25 38. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 37, said at least one gelling agent a carboxyvinyl polymer, a cellulose derivative, a xanthan gum, a guar gum, a polyacrylamide, or mixture thereof.

39. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 37, comprising from 0.05% to 5% by weight of said at least one gelling agent.

09381686 "051304

40. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, further comprising at least one sequestering agent, antioxidant, sunscreen, preservative, filler, dye or colorant, fragrance, essential oil, cosmetic active agent, moisturizer, vitamin, essential fatty acid, sphingolipid, artificial tanning agent, agent for soothing and protecting the skin, or mixture thereof.

41. A regime or regimen:

(1) for treating dermatological conditions/affliction associated with a keratinization disorder related to differentiation and proliferation, including common acne, comedones, polymorphonuclear leukocytes, rosacea, nodulocystic acne, acne conglobata, senile acne and secondary acne, including solar, medication-related or occupational acne, or

(2) for treating another keratinization disorder, including ichthyosis, an ichthyosiform state, Darier's disease, palmoplantar keratoderma, leukoplasmia, a leukoplasiform state, and cutaneous or mucous (buccal) lichen, or

(3) for treating another dermatological condition/affliction associated with a keratinization disorder manifesting an inflammatory and/or immunoallergenic component, including all forms of psoriasis, whether cutaneous, mucous or ungual psoriasis, psoriatic rheumatism, cutaneous atopy, eczema, respiratory atopy, gingival hypertrophy, or for treating inflammatory conditions which manifest no keratinization disorder, including rosacea, or

(4) for treating all dermal or epidermal proliferations, whether benign or malignant and whether of viral or non-viral origin, including common warts, flat warts, verruciform epidermodysplasia, oral or florid papillomatoses and proliferations induced by ultraviolet radiation, basocellular or spinocellular epithelioma, or

(5) for treating bullosis or a collagen disease state, or



(6) for repairing or combating aging of the skin, whether photoinduced or chronological aging, or for reducing pigmentations and actinic keratosis, or any pathology associated with chronological or actinic aging, or

5 (7) for preventing or curing the stigmata of epidermal and/or dermal atrophy induced by local or systemic corticosteroids, or other form of cutaneous atrophy, or

(8) for the preventive or curative treatment of cicatrization disorders, for preventing or repairing stretch marks, or for promoting cicatrization, or

10 (9) for combating disorders of sebaceous functioning, including acneic hyperseborrhoea or simple seborrhoea, or

(10) for the preventive or curative treatment of cancerous or precancerous disease states, or

(11) for the treatment of inflammatory conditions/afflictions, including arthritis, or

15 (12) for the treatment of any skin condition/affliction of viral origin, or

(13) for the preventive or curative treatment of alopecia, or

(14) for the treatment of dermatological conditions/afflictions manifesting an immunological component, or

20 (15) for the treatment of skin disorders caused by exposure to UV radiation, or

(16) for the treatment of dermatological conditions/afflictions associated with inflammation or infection of the tissues surrounding the hair follicles, including colonization or microbial infection, impetigo, seborrhoeic dermatitis, folliculitis, sycosis barbae, or

25 (17) for accelerating or promoting hair loss, comprising topically applying onto the skin, scalp and/or hair of a candidate subject in need of such treatment, for such period of time as required to elicit the desired biological response, a topically applicable cosmetic/pharmaceutical oil-in-water emulsion including a discontinuous fatty phase dispersed in a continuous aqueous phase and comprising

an effective amount of at least one thus-biologically active agent (A) and an effective amount of an emulsifying system (B) therefor, said at least one biologically active agent (A) being non-solubilized therein in micronized particulate state, at least 80%, numerically, of said micronized particles having diameters ranging from 1 to 10  $\mu\text{m}$  and at least 50%, also numerically, having diameters of less than 5  $\mu\text{m}$ .

42. The regime/regimen as defined by Claim 41, comprising preventively or curatively treating acne.

43. The regime/regimen as defined by Claim 1, said at least one biologically active agent (A) comprising an agent which modulates proliferation and/or differentiation, an antibiotic, an antibacterial agent, an antifungal agent, an antiparasitic agent, or mixture thereof.

44. The regime/regimen as defined by Claim 1, said at least one biologically active agent (A) comprising nadifloxacin, 6-[7-(1-adamantyl)-6-methoxyethoxymethoxy-2-naphthyl]nicotinic acid, 6-[3-(1-adamantyl-4-hydroxyphenyl)-2-naphthoic acid, 6-(3,5,5,8,8-pentamethyl-5,6,7,8-tetrahydro-2-naphthylthio)nicotinic acid, 3-(3,5,5,8,8-pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)phenylacrylic acid, 2-hydroxy-4-[7-(1-adamantyl)-6-methoxyethoxymethoxy-2-naphthyl]benzoic acid, or mixture thereof.

45. The regime/regimen as defined by Claim 1, said discontinuous fatty phase comprising at least one dry to moderately dry fatty oil.

46. The regime/regimen as defined by Claim 45, said at least one dry to moderately dry fatty oil comprising isohexadecane, dioctylcyclohexane, isopropyl palmitate, hydrogenated polyisobutene, diisopropyl adipate, dicaprylyl ether,

isopropyl myristate, dipropylene glycol dipelargonate, a C<sub>12</sub>-C<sub>15</sub> alkyl benzoate, cetostearyl isononanoate, cetostearyl ethylhexanoate, synthetic squalene, olive oil, octyl palmitate, octyldodecyl myristate, a caprylic/capric triglycerides, or mixture thereof.

5

47. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, having a pH ranging from 5 to 7.

10

48. The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 47, having a pH ranging from 5 to 6.

15

49. A regime or regiment for therapeutically treating inflammation or infection of the skin tissue surrounding hair follicles, comprising topically applying onto this skin tissue of a candidate subject in need of such treatment, for such period of time as required to elicit the desired biological response, a topically applicable cosmetic/pharmaceutical oil-in-water emulsion including a discontinuous fatty phase dispersed in a continuous aqueous phase and comprising an effective amount of at least one thus-biologically active agent (A) and an effective amount of an emulsifying system (B) therefor, said at least one biologically active agent (A) being non-solubilized therein in micronized particulate state, at least 80%, numerically, of said micronized particles having diameters ranging from 1 to 10  $\mu\text{m}$  and at least 50%, also numerically, having diameters of less than 5  $\mu\text{m}$ .

20

09831686-061301